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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Draft National Toxicology Program (NTP) Monograph on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use during Pregnancy; Request for Comments; Peer Review Panel Meeting

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health

ACTION: Notice

Date: The peer review meeting will take place October 1, 2012, 1:00 to 5:00 PM Eastern Daylight Time (EDT) and October 2, 2012, from 8:30 AM until adjournment, approximately 5:00 PM. Two days are set aside for the meeting; however, it may adjourn sooner if the panel completes its peer review of the draft monograph.

Topic: Peer review of the draft NTP Monograph on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use during Pregnancy (available by August 14, 2012, at <http://ntp.niehs.nih.gov/go/36639>).

Place: Rodbell Auditorium, Rall Building, NIEHS, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709. The meeting is open to the public with attendance limited only by the space available. Webcast of the meeting will be available at <http://www.niehs.nih.gov/news/video/index.cfm>.

Contact Person: Dr. Mary S. Wolfe, NTP Designated Federal Official, Office of Liaison, Policy and Review, DNTP, NIEHS, P.O. Box 12233, MD K2-03, Research Triangle Park, NC 27709,

PHONE: (919) 541-7539, FAX: (919) 541-0295, or *wolfe@niehs.nih.gov*. Courier address: 530 Davis Drive, Room 2142, Morrisville, NC 27560.

Request for Comments and Registration: The meeting is open to the public with time scheduled for oral public comment. The NTP also invites written comments on the draft monograph, submission deadline is September 14, 2012, and the deadline for pre-registration to attend the meeting and/or provide oral comments is September 24, 2012, online registration is available at <http://ntp.niehs.nih.gov/go/36639>. Visitor and security information is available at <http://www.niehs.nih.gov/about/visiting/index.cfm>. Public comments and any other correspondence on the draft monograph should be sent to the Contact Person. Individuals with disabilities who need accommodation to participate in this event should contact Danica Andrews at phone: (919) 541-2595 or email: *andrewsda@niehs.nih.gov*. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

SUPPLEMENTARY INFORMATION:

Background

The panel will peer review the Draft NTP Monograph on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use during Pregnancy, prepared by the Office of Health Assessment and Translation (OHAT), DNTP. Cancer diagnosed during pregnancy affects approximately 1/6000 to 1/1000 women. Treatment for cancer frequently involves chemotherapy, and nearly all chemotherapeutic agents are known developmental toxicants in laboratory animals. OHAT has prepared a comprehensive draft NTP Monograph that summarizes the effects on development and pregnancy outcomes of gestational exposure to 52 cancer chemotherapeutic agents, individually and/or in combination therapy as reported in the peer-

reviewed literature. The draft monograph also provides information on seven frequently diagnosed cancers in pregnant women and on mechanism of action, placental and breast milk transport, and laboratory animal developmental toxicology for the more frequently used chemotherapeutic agents. The overall goal of the monograph is to serve as a resource for the medical communities and their patients.

Preliminary Topic and Availability of Meeting Materials

The preliminary agenda and draft monograph should be posted on the NTP website (<http://ntp.niehs.nih.gov/go/36639>) by August 14, 2012. Additional information, when available, will be posted on the NTP website or may be requested in hardcopy from the Contact Person. Following the meeting, a report of the peer review will be prepared and made available on the NTP website. Registered attendees are encouraged to access the meeting page to stay abreast of the most current information regarding the meeting.

Request for Comments

The NTP invites written comments on the draft monograph, which should be received by September 14, 2012, to enable review by the peer review panel and NTP staff prior to the meeting. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and/or sponsoring organization.

Public input at this meeting is also invited, and time is set aside for the presentation of oral comments on the draft monograph. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The available lines will be open from

1:00 - 5:00 PM EDT on October 1 and from 8:30 until adjournment on October 2, although oral comments will be received only during the formal public comment period indicated on the preliminary agenda. Each organization is allowed one time slot. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the chair. Persons wishing to make an oral presentation are asked to register online at <http://ntp.niehs.nih.gov/go/36639> by September 24, 2012, and if possible, to send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register on-site.

Background Information on OHAT and NTP Peer Review Panels

The NIEHS/DNTP established OHAT to serve as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. OHAT assessments are published as NTP Monographs. Information about OHAT is found at <http://ntp.niehs.nih.gov/go/ohat>.

NTP panels are technical, scientific advisory bodies established on an "as needed" basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions

about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide a current *curriculum vitae* to the Contact Person. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: August 8, 2012

John R. Bucher, Ph.D.

Associate Director, National Toxicology Program

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